UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 6, 2000

Ms. Lizbeth A. Rea
Registration Manager, RPAC
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Dear Ms. Rea:

The Agency has provided you with a 30-day period to identify and comment on any errors in the Preliminary Human Health Risk Assessment for phosalone. Errors include, but are not limited to, mathematical, computational, typographic, or other similar errors.

We have carefully reviewed your comments and have revised the risk assessment accordingly. Most of comments pertained to data which RPAC plans to submit in order to fulfill data gaps in the generic data base for phosalone. The attached table is a summary of your comments and the Agency's response to them.

If you have any questions, please contact me at (703) 308-7043.

Sincerely,

Deanna Scher
Chemical Review Manager
Special Review and
Reregistration Division

Attachment

Phosalone Preliminary Human Health Risk Assessment
Comment/Response Summary

Comment	Response
Product Chemistry Requirements: RPAC plans to submit additional product chemistry information to fulfill the data gaps (gdln. #'s 830.1600, 830.1670, 830.7050) identified in the Reregistration Eligibility Decision Residue Chemistry Chapter for phosalone.	The Agency has received the information intended to fulfill these data gaps. The data are currently in review.
Toxicology data requirements: RPAC plans to conduct a study for an unscheduled DNA synthesis (UDS) to confirm questionable results in the submitted study. The time frame for completing this study has not yet been confirmed.	The Agency recommends that the assay be repeated to confirm or refute the findings of this study. Since the study is classified as acceptable and satisfies the requirements for FIFRA Test Guideline 870.5375, the repeat study is a recommendation rather than a requirement.
In regards to the upgradable rat metabolism study (Guideline 870-7485), RPAC is unable to provide the requested additional data on metabolite identification in urine due to the unavailability of samples for further analysis. However, a full study is planned for initiation in approximately April 2000, with completion about June 2001.	The Agency will send RPAC a letter shortly which will provide a deadline for submitting a new study to fulfill Guideline 870-7485. The Agency generally provides the registrant 2 years to complete a new rat metabolism study.
Rhone-Poulenc believes that an error was made regarding the need for a developmental neurotoxicity study for phosalone. Phosalone was not subject to the recent Data Call-in Notice which called in neurotoxicity data for all organophosphates.	EPA recently issued a Data Call-in Notice to registrants of neurotoxic pesticides, beginning with the cholinesterase-inhibiting organophosphates, requiring the submission of acute subchronic, and developmental neurotoxicity studies (August 6, 1999 64FR42945-42947 and August 18, 1999 64FR44922-44923). Since all phosalone U.S. registrations were voluntarily withdrawn in 1989,it was not included in the DCI Notice. However, the Agency plans to publish a Federal Register Notice shortly which will require that registrants of organophosphates with "import tolerances" submit the three neurotoxicity studies as well. The text will be corrected to clarify that phosalone was not included in the Data Call-in Notice.
Residue Chemistry Requirements: RPAC believes that the additional data requirements beyond the currently available, and soon to be completed field trial data are unnecessary, given market share and potential treated imported commodities, and will request a meeting with the Agency to discuss this further.	16 additional field trials are necessary to support import tolerances in/on apples, pears, cherries, peaches, plums and grapes. These requirements will be the focus of discussion at the January 6, 2000 meeting between the Agency and Rhone-Poulenc. Any amendments to the requirements resulting from the meeting will be documented in the meeting minutes and placed in the docket.